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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,422	11/01/2000	Ronald N. Zuckermann	CHIRP012/1613.002	4637
27476 75	590 04/23/2003			
Chiron Corporation Intellectual Property - R440 P.O. Box 8097			EXAMINER	
			PADMANABHAN, KARTIC	
Emeryville, CA 94662-8097			ART UNIT	PAPER NUMBER
			1641	14
			DATE MAILED: 04/23/2003	17

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		09/704,422	ZUCKERMANN ET AL.			
		Examiner	Art Unit			
		Kartic Padmanabhan	1641			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address					
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1)						
2a)⊠	` `	is action is non-final.				
3)	, <u> </u>					
Disposition of Claims						
•	)⊠ Claim(s) <u>1-25,74 and 75</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
,	Claim(s) is/are allowed.					
·	☑ Claim(s) <u>1-25,74 and 75</u> is/are rejected.					
·	Claim(s) is/are objected to.					
	Claim(s) are subject to restriction and/or ion Papers	r election requirement.				
		r				
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
.0/	Applicant may not request that any objection to the	•				
11) 🔲 :	The proposed drawing correction filed on		• •			
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
	1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No					
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>						
Attachment(s)						
2) 🔲 Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)			

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#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 112

- 1. Claims 1-25 and 74-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 2. The term "intermediate" in claim 1 is a relative term which renders the claim indefinite.

  The term "intermediate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

# Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-25 and 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zuckermann et al. (WO 98/42730). The reference teaches methods of preparing substrates, wherein the substrates may be used in screening and/or separation procedures. According to the reference, the substrate surface contains a plurality if hydrophilic sites that can be protected or deprotected. The hydrophilic groups of the reference may be selected from hydroxyls, carboxyls, thiols, amines, and mixtures thereof. The substrates of the reference may also have an organic compound bound to the hydrophilic moieties, wherein the organic compound is a ligand. The ligand may be oligomeric, such as an oligonucleotide, oligopeptide, or oligopeptoid. The separation/screening process includes the step of contacting a sample with the support-bound ligand, which can bind to a component therein. In addition, a plurality of chemically distinct ligands may be provided on the support, such that a ligand of interest may be identified by screening for said ligand. The screening/separation procedure may be a chromatographic separation. Sample, according to the reference is any material in fluid form that has a component of interest. The analyte to be assayed or screened for may be enzymes, oligonucleotides, and others. However, the reference does not teach the specific affinity groups or ligands required, the percent of affinity groups, or the nature of the sample.

It would have been prima facie obvious to one of ordinary skill in the art at the time of

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the invention to use specific affinity groups and ligands, a certain percent of affinity groups in the backbone, and any number of different samples with the method of Zuckermann et al. It would have been obvious to use the specific affinity groups required of the pending claims because the reference generally discloses alkyls. It would have also been obvious to use ligands with intermediate binding affinity because the reference generally discloses ligands with various binding affinities. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Also, in terms of the selection of ligands with intermediate binding affinity, it would have been obvious to select ligand(s) with a specific binding affinity, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272; 205 USPQ 215 (CCPA 1980). Or, if the intermediate binding affinity can constitute a range of values for binding, it would have been obvious to select ligands that exhibit an affinity within this range because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Further, it would have been obvious to use a specific percentage of affinity groups because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Finally, it would have also been obvious to use the specific samples required by the claims because the reference teaches any sample, preferably fluid, containing the analyte of interest is suitable. Therefore, selection of a specific sample simply represents an optimization of the assay protocol and does not patentably distinguish the claimed invention over the prior art.

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## Response to Arguments

- 7. Applicant's arguments filed 4/7/03 have been fully considered and are persuasive to overcome the rejection under 35 USC 102 over the Zuckermann reference; however, the reference has now been applied solely under 35 USC 103.
- 8. The examiner acquiesces to applicant's arguments that the Zuckermann reference does not specifically teach ligands with an intermediate level of binding affinity, but maintains that such a limitation would have been obvious to one of skill in the art at the time of the invention. The selection of specific ligands merely represents an optimization of the assay and does not patentably distinguish the invention over the prior art of record. Applicant is directed to the rejection under 35 USC 103 above, with attention to the case law cited therein, for a more detailed discussion of the rationale relied upon.

#### Conclusion

Claims 1-25 and 74-75 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan

Patent Examiner

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April 15, 2003

LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

04/25/03